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TREATMENT OF ALZHEIMER'S DISEASE, and which is incorporated herein by reference.--

REMARKS

Claims 1-37 are pending in the application. Claim 1-21 and 30-37 are withdrawn from consideration as directed to another invention. Claims 22-29 are presently under examination.

As requested in the current Office Action (Paper No. 9), the specification has been amended in the first paragraph to recite the serial number assigned to the provisional application of which the present application claims the benefit of priority. Applicants have set forth above the amendment to the specification in clean form above. The amendment does not raise an issue of new matter and entry thereof is respectfully requested.

Regarding the Rejections under 35 U.S.C. § 112

A. First Paragraph

The objection to the specification and rejection of claims 22-26, 28 and 29 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description respectfully is traversed. The Office asserts at page 5, second full paragraph, of the Action (Paper No. 9) that it appears at the time the application was filed Applicants were not in possession of the parental strains encompassed by the claims, other than

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*Drosophila*. For the reasons that follow, Applicants submit that, at the time of filing, Applicants had possession of the full scope of the claimed methods of identifying a therapeutic agent for treating Alzheimer's disease.

The Office cites *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 U.S.P.Q.2d 1398 (Fed. Cir. 1997), to support the proposition that the genus of parental strains encompassed by Applicants' claims is not described in sufficient detail to allow the skilled person to conclude Applicants were in possession of the claimed invention. Applicants respectfully remind the Office that at issue in *Regents of the University of California v. Eli Lilly & Co.*, were genus claims directed to human, vertebrate, and mammalian cDNA based on recitation of the nucleotide sequence of rat proinsulin cDNA, a disclosure which the Federal Circuit held was not sufficient to satisfy the written description requirement. *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d at 1562, 43 U.S.P.Q.2d at 1402. The Federal Circuit in that decision provided some guidance as to what level of specificity is required for nucleotide claims. *Id.* at 1569, 43 U.S.P.Q.2d at 1406. In contrast, the invention claimed in the present application is directed to method claims of which Applicants show possession of the full scope by virtue of the headings provided in the specification and summarized in brief below. In other words, the standards imposed by paragraph 112 of the Code as they relate to the pathway of nucleotide compositions be mechanically applied to method claims by taking out of context the Federal Circuit's decision in Eli Lilly.

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In *In re Edwards*, the C.C.P.A. articulated the function of the written description requirement, stating:

[The f]unction of [the] description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; to comply with the description requirement, it is not necessary that the application describe the claimed invention in *ipsis verbis*; all that is required is that it reasonably convey to persons skilled in the art that, as of the filing date thereof, the inventor had possession of the subject matter later claimed by him.

*In re Edwards*, 568 F.2d at 1351-52, 196 U.S.P.Q. at 467 (citations omitted).

Applicants respectfully submit that the specification conveys to the skilled person that, at the time of filing, Applicants had possession of the claimed methods of identifying a therapeutic agent for treating Alzheimer's disease. As taught in the specification, while the methods of the invention are exemplified using the genetic system *Drosophila*, any genetic system suitable for transmission genetics and convenient analysis of test and sibling control progeny is useful for practicing the methods of the invention (page 17, lines 1-10). In this regard, the specification further teaches that examples of genetic systems suitable for practicing the methods of the invention include, for example, mice (*Mus musculus*), zebrafish (*Danio rerio*), nematodes (*Caenorhabditis elegans*), and yeast

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(*Saccharomyces cerevisiae* and *Schizosaccharomyces pombe*) (page 17, lines 1-10).

At the time of filing, those skilled in the art had knowledge that human disease gene homologs had been identified in a variety of genetic systems and, given the broad teachings and guidance for the use and applicability of the claimed methods with regard to species other than *Drosophila*, would have appreciated Applicants possession of the full scope of the claimed invention. In this regard the specification teaches, for example, at page 17, lines 14-29, homologs of human disease genes in a variety of other genetic systems including zebrafish, nematodes and yeast. Furthermore, for the various embodiments, the specification provides guidance with regard to practicing the invention in strains corresponding to a variety of genetic systems, for example, at page 39, lines 19-26, which discusses particular modes of administering an agent to mice, nematodes zebrafish and yeast. With regard to phenotypes useful for practicing the invention, the specification teaches that useful phenotypes include the size, viability, eye color, coat color, or exploratory behavior of mice; the size, viability, skin color, or optomotor response of zebrafish; the size, viability, phototaxis or chemotaxis of nematodes; and the colony color, colony size or growth requirements of yeast. These teachings would have conveyed to the skilled person, at the time of filing, that Applicants, while exemplifying the claimed methods using *Drosophila*, were in possession of the full scope of their claimed invention, which includes practice of the methods of identifying

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a therapeutic agent for treating Alzheimer's disease, in strains other than *Drosophila*.

In view of the above, Applicants request that the Office withdraw the objection to the specification and rejection of claims 22-26, 28 and 29 under 35 U.S.C. § 112, first paragraph, as allegedly lacking written description.

B. Second Paragraph

The rejection of claims 22-29 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to point out and distinctly claim the subject matter regarded as the invention respectfully is traversed.

A seminal case on the construction of the second paragraph of § 112 is *In re Borkowski*, 422 F.2d 904, 164 U.S.P.Q. 642 (C.C.P.A. 1970), where the CCPA observed:

The first sentence of the second paragraph of § 112 is essentially a requirement for precision and definiteness of claim language. If the scope of subject matter embraced by a claim is clear, and if the applicant has not otherwise indicated that he intends that claim to be of a different scope, then the claim does particularly point out and distinctly claim the subject matter which the applicant regards as his invention.

*Id.* at 909, 164 U.S.P.Q. at 645-46 (footnote omitted).

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The importance of the above-cited language of *Borkowski* is that a claim that is understandable to one skilled in the art and that defines subject matter that applicant regards as the invention meets the requirements of 35 U.S.C. § 112, second paragraph. The Federal Circuit has consistently made it clear that definiteness of claim language must be analyzed, not in a vacuum, but in light of (1) the content of the particular application disclosure, (2) the teachings of the prior art, and (3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See, e.g., *In re Marosi*, 710 F.2d 799, 218 U.S.P.Q. 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 U.S.P.Q. 1 (Fed. Cir. 1984); *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983); and *Atmel Corp. v. Information Storage Devices, Inc.*, 198 F.3d 1374, 53 U.S.P.Q.2d 1225 (Fed. Cir. 1999) (district court failed to consider the knowledge of one skilled in the art when interpreting the patent disclosure). As recently noted in *S3 Inc. v. nVidia Corp.*, 259 F.3d 1364, 59 U.S.P.Q.2d 1745 (Fed. Cir. 2001):

The purpose of claims is not to explain the technology or how it works, but to state the legal boundaries of the patent grant. A claim is not "indefinite" simply because it is hard to understand when viewed without benefit of the specification.

*Id.* at 1369. [Emphasis added]

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Here, the meaning of the phrase "a modification of the altered phenotype producing a phenotype with more similarity to a wild type phenotype than the altered phenotype has to the wild type phenotype" would have been clear to the skilled person based on both the state of the prior art as well as on the teachings in the specification. In particular, the specification clearly defines the terms "phenotype" and "altered phenotype" such that it would have been clear to the skilled person having read the specification what is meant by a phenotype with more similarity to a wild type phenotype than the altered phenotype has to the wild type.

With regard to providing clarity, the specification, for example, at page 5, lines 1-5, teaches that the methods of the invention can be practiced by assaying for an altered phenotype such as altered viability, morphology or behavior in test progeny produced by mating two parent strains of, for example, *Drosophila melanogaster*. Furthermore, at page 33, lines 1-16, the specification defines the term "phenotype" as referring to the physical appearance or observable properties of an individual that are produced, in part, by the genotype of the individual and teaches that a variety of behavioral, morphological and other physical phenotypes are useful in the methods of the invention including *Drosophila* phenotypes such as eye color, wing shape, bristle appearance, size, phototaxis and viability. With regard to genetic systems other than *Drosophila*, the specification teaches that additional phenotypes useful for practicing the invention include the size, viability, eye color, coat color, or exploratory behavior of mice; the size, viability,

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skin color, or optomotor response of zebrafish; the size, viability, phototaxis or chemotaxis of nematodes; and the colony color, colony size or growth requirements of yeast (specification, page 33, lines 10-16).

With regard to the term "altered phenotype" as used in reference to the phenotype of test progeny as compared to a sibling control, the specification teaches that the term means a significant change in the physical appearance or observable properties of the test progeny as compared to a sibling and is used broadly to encompass both a phenotype that is dramatically changed as compared to the phenotype of a sibling control as well as a phenotype that is slightly but significantly changed as compared to a sibling control (specification ,page 34, lines 4-13) .

With regard to the comparison of phenotypes, the specification teaches that it is recognized that there can be natural variation in the phenotypes of test progeny, but provides further specific guidance by teaching that the altered phenotype readily can be identified by sampling a population of test progeny and determining that the normal distribution of phenotypes is changed, on average, as compared to the normal distribution of phenotypes in a population of sibling controls (specification, page 34, lines 14-20). Providing further clarity regarding the comparison of pehonotypes, the specification teaches that where a phenotype can be quantified, the alteration will be statistically significant and generally will be an increase or decrease of at least about 5%, 10%, 20%, 30%, 50% or

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100% as compared to sibling controls (specification, page 34, lines 20-24). Comparison of quantifiable traits is further demonstrated in Example I, where viability scores less than 80% or more than 110% of sibling controls carrying one copy of *Appl<sup>d</sup>* were considered statistically significant examples of an "altered phenotype." (specification, page 34, lines 24-28) Thus, the specification provides detailed teachings that clearly and distinctly define the meaning of the phrase "a modification of the altered phenotype producing a phenotype with more similarity to a wild type phenotype than the altered phenotype has to the wild type phenotype."

In view of the above, Applicants submit that the claims 22-29 would have been clear and definite to the skilled person based on both the state of the prior art and on the teachings in the specification. Accordingly, Applicants request that the Office withdraws the rejection of claims 22-29 under 35 U.S.C. § 112, second paragraph, as allegedly indefinite for failing to point out and distinctly claim the subject matter regarded as the invention.

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The Examiner is invited to call the undersigned attorney or Cathryn Campbell if there are any questions.

Respectfully submitted,



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March 6, 2003

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